



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Yu et al.

Docket No.: PF343P3C5

Application No.: 09/589,288

Confirmation No.: 1519

Filed: June 8, 2000

Art Unit: 1647

For: Methods of Inhibiting B Lymphocytes Using
Antibodies to Neutrokine-alpha (As Amended)

Examiner: B. E. Bunner

INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of a claim of the subject application, Agent for Applicants hereby directs the Examiner's attention to references J1-J99 listed on the attached Form SB/08. Copies of non-U.S. patent references J22-J29, J71-J72 and J81-J99 are enclosed.

Copies of references J30, and J37-J40 were previously submitted to the Patent and Trademark Office with Applicants' Information Disclosure Statement filed June 10, 2005. Copies of references J31-35, J41-J59 were previously submitted to the Patent and Trademark Office with Applicants' Information Disclosure Statement filed August 26, 2005. Copies of references J36 and J60-J70 were previously submitted to the Patent and Trademark Office with Applicants' Information Disclosure Statement filed September 23, 2005. Should the Examiner require additional copies of any of these references, please contact the undersigned.

Copies of references J73-J80 were submitted by Applicants or cited by the Examiner in connection with U.S. Application No. 09/507,968, filed on February 23, 2000, to which the instant application claims priority under 35 U.S.C. § 120. Pursuant to

37 C.F.R. § 1.98(d), the Examiner is directed to the file of U.S. Application No. 09/507,968 for copies of references J73-J80. However, should the Examiner require additional copies of any of these references, please contact the undersigned.

Identification of the listed references is not to be construed as an admission of any individual associated with the filing or prosecution of the subject application that such references are available as "prior art" against the subject application. Furthermore, Applicants do not waive any rights to take appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the subject application.

The listed references are presented so that the Patent and Trademark Office can determine any materiality thereof to the claimed invention. See 37 C.F.R. § 1.104(a) concerning the Examiner's duty to consider and use any such information. Applicants respectfully request that the Examiner make the listed references of record in the file history of the application, and consider the information contained therein during the prosecution of this application.

Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a Request for Continued Examination. Accordingly, no fee is believed due. However, should the Patent Office determine otherwise, please charge such fee to our Deposit Account No. 08-3425.

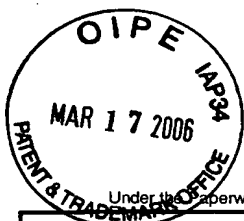
Dated: March 17, 2006

Respectfully submitted,

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PTO/SB/08a/b (07-05)
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	09/589,288	
			Filing Date	June 8, 2000	
			First Named Inventor	Guo-Liang Yu	
			Art Unit	1647	
			Examiner Name	B.E. Bunner	
Sheet	1	of	5	Attorney Docket Number	PF343P3C7

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	J1	US2002/0037852 A1	03-28-2002	Browning et al.	
	J2	US2002/0150579 A1	10-17-2002	Kimberly et al.	
	J3	US2003/0059937 A1	03-27-2003	Ruben et al.	
	J4	US2003/0095967 A1	05-22-2003	MacKay et al.	
	J5	US2003/0148445 A1	08-07-2003	Shu	
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	J12	6,689,579	02-10-2004	Yu et al.	
	J13	6,716,576	04-06-2004	Yu et al.	
	J14	09/302,863	NA	Immunex Corp.	
	J15	60/149,378	NA	Mackay, F., et al.	
	J16	09/255,794	NA	Yu, G., et al.	
	J17	60/119,906	NA	Boyle, W. and Hsu, H.	
	J18	60/166,271	NA	Boyle, W. and Hsu, H.	
	J19	09/226,533	NA	Gross, J., et al.	
	J20	60/157,933	NA	Schneider, P., et al.	
	J21	5,595,721	01-21-1997	Kaminski et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	J22	WO99/35170 A2	07-15-1999	Genentech, Inc.		
	J23	WO01/87977 A3	11-22-2001	Amgen, Inc.		
	J24	WO01/60397 A1	08-23-2001	Genentech, Inc.		
	J25	WO04/074511 A1	09-02-2004	Garvan Institute of Medical Research		
	J26	WO05/005462 A3	01-10-2005	Genentech, Inc.		
	J27	WO05/042009 A1	05-12-2005	Biogen IDEC MA, Inc.		
	J28	EP 1 354 598 A3	10-22-2003	ZymoGenetics, Inc.		
	J29	EP 1 415 659 A1	05-06-2004	Biogen, Inc. and Apoxis SA		
	J30	EP 1 146 892 B1	08-20-2003	Biogen, Inc., Apoxis SA		
	J31	EP 1 141 274 B1	09-10-2003	ZymoGenetics, Inc.		
	J32	WO98/39361 A1	09-11-1998	St. Jude Children's Research Hospital		
	J33	WO01/12812 A2	02-22-2001	Biogen, Inc. and Apotech R & D SA		
	J34	WO01/24811 A1	04-12-2001	Biogen, Inc. and Apotech R & D SA		
	J35	WO02/066516 A3	08-29-2002	ZymoGenetics, Inc.		

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	J36	EP 9828628.9	NA	Glaxo Group Ltd.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	J37	Human Genome Sciences' opposition of EP Patent No 1 146 892 B1 including Annex A. Filed in the European Patent Office on September 19, 2005.	
	J38	Serono International SA's opposition of EP Patent No 1 146 892 B1 with Annexes I and II. Filed in the European Patent Office on August 24, 2005	
	J39	Lexikon der Medizin "Hypertension"	
	J40	WALLACH, D. "TNF Ligands and TNF/NGF Receptor Families" in Cytokine Reference Vol.1: Ligands, eds. Oppenheim and Feldman, Academic Press, pp. 377-411. (2001).	
	J41	Corixa Corporation's opposition of EP Patent No 1 141 274 B1. Filed in the European Patent Office on June 6, 2004.	
	J42	Human Genome Science's opposition of EP Patent No 1 141 274 B1. Filed in the European Patent Office on June 7, 2004.	
	J43	Genentech's opposition of EP Patent No 1 141 274 B1. Filed in the European Patent Office on June 10, 2004.	
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	J51	Table setting out SEQ ID Nos (provided by Opponent I).	
	J52	PATEL ET AL., "Engineering an APRIL-specific B cell maturation antigen" <i>The Journal of Biological Chemistry</i> , 279:16727-16735. (2004).	
	J53	MUKHOPADHYAY ET AL., "Identification and characterization of a novel cytokine, THANK, a TNF Homologue that activates Apoptosis, Nuclear factor-kappaB, and c-Jun NH2-terminal Kinase" <i>The Journal of Biological Chemistry</i> , 274:15978-15981. (1999).	
	J54	Clustal V Alignment of human and mouse TACI (provided by Opponent I).	
	J55	BODMER ET AL., "The molecular architecture of the TNF superfamily" <i>Trends in Biochemical Sciences</i> , 27:19-26. (2002).	

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	J56	HYMOWITZ, ET AL., "Structures of APRIL-receptor complexes: like BCMA, TACI employs only a single cysteine-rich domain for high affinity ligand binding" <i>The Journal of Biological Chemistry</i> , 280:7218-7227, (2005), with Tables S1-S4 and Fig. S1 as published in the online version of this article available at http://www.jbc.org .	
	J57	Sequence alignment of "Prosite" sequence (D1) and SEQ ID NO: 10 of EP 1 141 274 B1.	
	J58	Further experimental evidence concerning anti-TACI antibodies of [EP 1 141 274 B1] Patent Example 18 (Zymogenetics' unpublished data).	
	J59	GROSS ET AL., "TACI-Ig neutralizes molecules critical for B cell development and autoimmune disease: Impaired B cell maturation in mice lacking BLyS" <i>Immunity</i> , 15:289-302. (2001).	
	J60	Human Genome Science Inc.'s Reply filed in the European Patent Office on September 19, 2005 in conjunction with its Opposition of EP Patent No 1 146 892.	
	J61	DELVES AND ROITT, Encyclopedia of Immunology. 2 nd ed. Academic Press Inc. pp 1554-1559. (1998).	
	J62	JANEWAY AND TRAVERS, Immunobiology: The Immune System in Health and Disease. Current Biology Ltd./Garland Publishing, London. pp 5:28. (1994).	
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				Art Unit	1647
				Examiner Name	B.E. Bunner
Sheet	4	of	5	Attorney Docket Number	PF343P3C7

NON PATENT LITERATURE DOCUMENTS				
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	J77	SMITH ET AL., "The challenges of genome sequence annotation or 'The devil is in the details'", <i>Nature Biotechnology</i> , 15:1222-3. (1997).		
	J78	DOERKS ET AL., "Protein Annotation: Detective Work for Function Prediction", <i>Trends in Genetics</i> , 14:248-250. (1998).		
	J78	BRENNER, S.E., "Errors in Genome Annotation" <i>Trends in Genetics</i> , 15:132-3. (1999).		
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	J90	LIU ET AL., "Ligand receptor binding revealed by the TNF family member Tall-1" <i>Nature</i> , 423:49-56. (2003).		
	J91	HEPPELER ET AL., "Receptor Targeting for Tumor Localisation and Therapy with Radiopeptides" <i>Current Medicinal Chemistry</i> , 7:971-994. (2000).		
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	J97	LOTZ ET AL., "The nerve growth factor/tumor necrosis factor receptor family" <i>Journal of Leukocyte Biology</i> , 60:1-7. (1996).		

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				Art Unit	1647
				Examiner Name	B.E. Bunner
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Sheet	5	of	5		

NON PATENT LITERATURE DOCUMENTS				
	J98	Molecular Biology of the Cell, Second Edition, edited by Alberts et al., Garland Publishing, Inc., New York, pp. 117-118. (1989).		
	J99	MARIETTE ET AL., "The Level of BLyS (BAFF) Correlates With the Titre of Autoantibodies in Human Sjogren's Syndrome" <i>Annual Rheumatology Discussion</i> , 62:168-171. (2003).		

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Sheet 1 of 1

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NON PATENT LITERATURE DOCUMENTS

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	C1	Waldmann, TA, "Immunotherapy: Past, Present and Future," Nature Medicine 9:269-277, (2003).	
	C2	Janeway, C. & P. Travers. (1994) Immunobiology: The Immune System in Health and Disease, (Current Biology Ltd./Garland Publishing, London), pp 1:15, 1:16 and 11:19.	
	C3	Weinblatt, ME et al., Methotrexate in rheumatoid arthritis. A five-year prospective multicenter study. Arthritis and Rheumatism. (1994) 37:1492-1498.	
	C4	Wise, CM et al., Methotrexate in nonrenal lupus and undifferentiated connective tissue disease - a review of 36 patients. The Journal of Rheumatology. (1996) 23:1005-1010.	
	C5	Brazelton, TR and RE Morris. Molecular mechanism of action of new xenobiotic immunosuppressive drugs: tacrolimus (FK506), sirolimus (rapamycin), mycophenolate mofetil and leflunomide. Current Opinion in Immunology. (1996) 8:710-720.	
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	D1	Baker et al., "Generation and Characterization of LymphoStat-B, a Human Monoclonal Antibody That Antagonizes the Bioactivities of B Lymphocyte Stimulator," <i>Arthritis & Rheumatism</i> , 48(11):3253-3265 (Nov. 2003).	
	D2	Furie, R. et al., "Safety, Pharmacokinetic and Pharmacodynamic Results of a Phase 1 Single and Double Dose-Escalation Study of LymphoStat-B (Human Monoclonal Antibody to BLyS) in SLE Patients." 67th Annual American College of Rheumatology Scientific Meeting, October 23-28, 2003, Orlando, Florida.	

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	09/589,288-Conf. #1519	
			Filing Date	June 8, 2000	
			First Named Inventor	Guo-Liang Yu	
			Art Unit	1647	
			Examiner Name	B. E. Bunner	
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	E1	6,869,605	03-22-2005	Browning et al.	
	E2	6,875,846	04-05-2005	Rennert et al.	

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	E3	Biogen Inc. and Apoxis SA's Response (including Annexes A and B and the Main Request containing a substitute set of claims) to Human Genome Sciences and Serono's Oppositions of EP Patent No. 1146892. The Response was filed in the European Patent Office on March 14, 2005.		

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	F1	WO-00/58362	10-05-2000	HUMAN GENOME SCIENCES, INC.		

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	F2	WPI/DERWENT Accession No. 2000-572093.	
	F3	Supplementary Partial European Search Report, European Application No. EP 00 90 8739, mailed June 30, 2005.	

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	G1	ZymoGenetics' Observations in Reply (158 pages) to Oppositions of EP Patent No. 1141274 lodged by Corixa Corporation, Human Genome Sciences, inc., Genentech, Inc., and Biogen Idec, Inc. The Observations in Reply was filed in the European Patent Office on June 7, 2005.	
	G2	STOHL, W., "A therapeutic role for BLYS antagonists," <i>Lupus</i> , 13:317-322 (2004).	
	G3	NOVAK et al., "Expression of BLYS and its receptors in B-cell non-Hodgkin lymphoma: correlation with disease activity and patient outcome," <i>Blood</i> , 104(8):2247-2253 (2004).	
	G4	European Search Report, European Application No. EP 05 01 2261, mailed August 8, 2005.	

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	11	WO-02/18620	03-07-2002	Human Genome Sciences, Inc.		

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	12	SCHALLER et al., "Characterization of <i>apxIVA</i> , a new RTX determinant of <i>Actinobacillus pleuropneumoniae</i> ," <i>Microbiology</i> , 145:2105-2116 (1999).	
	13	CHEN et al., "Expression vectors for affinity purification and radiolabeling of proteins using <i>Escherichia coli</i> as host," <i>Gene</i> , 139:73-75 (1994).	
	14	Supplementary European Search Report, European Application No. 02 78 6413, mailed December 20, 2005.	
	15	Human Genome Sciences, Inc.'s Reply filed in the European Patent Office on November 4, 2005 in conjunction with its Opposition of EP Patent No. 1141274 and copies of supporting documents D41-D43.	

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